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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,399	09/25/2003	Linda Pilarski	A894635US	1833

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,399	PILARSKI ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 9-25-03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-105 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-50 and 88-90, drawn to methods to detect the expression of isoenzyme variants in a cell or cell population comprising detecting the presence of a complex formed between an agent and the HAS isoenzyme variant genomic product, a method to detect expression of HAS1 variants comprising detecting the presence of an increased number of DNA fragments, a method to detect the expression of HAS1Va isoenzyme variant in a cell or cell population comprising detecting a SNP of the HAS1Va gene, a method to detect disease or disease susceptibility comprising characterizing HAS isoenzyme and isoenzyme variant expression in a cell or cell population, a method to detect disease susceptibility comprising detecting a SNP of the HAS1Va gene and a method to monitor malignant cells in a patient comprising detection of HAS isoenzymes or isoenzyme variants in a sample of cells or cell populate form a human, classified in class 435, subclasses 6 and 7.1.

II. Claims 51-61 and 91-100, drawn to a isolated DNA comprising a DNA fragment encoding a HAS variant, wherein the DNA hybridized to SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9 or SEQ ID NO:10 and kits comprising nucleotides which hybridize to HAS isoenzymes or HAS isoenzyme variant transcripts, classified in class 536, subclasses 23.1 and 24.3.

III. Claims 63-67 and 76-80, drawn to a method of treating a patient experiencing a disease or susceptible to disease comprising administrating compound resulting in diminished HAS1 through decreasing mRNA translation by binding to mRNA, classified in, for example, class 514, subclass 44.

IV. Claims 68-74 and 81-87, drawn to a method of treating a patient experiencing a disease or susceptible to disease comprising administrating compound resulting in decrease activity HAS1 protein, classified in, for example, class 424, subclass 184.1

V. Claims 101-105, drawn to a kit comprising characterizining peptide capable of binding to and distinguishing HAS IIsoenzymes or isoenzyme variants, class 530, subclass 350.

Claims 62 and 75 link inventions III and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 62 or 75 Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to exami-nation in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutorydouble patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group II can be used to express protein, as opposed to being used to hybridize to a gene transcript to identify the gene expression.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications.

Moreover, in the instant case, the searching isoenzyme variant DNA sequence and a method of using isoenzyme variant DNA is not coextensive. Prior art which teaches an isoenzyme variant DNA sequence would not necessarily be applicable to the method of using the isoenzyme variant DNA. Moreover, even if the isoenzyme variant DNA was known, the method of using the DNA to detect the expression of isoenzyme variants in particular cells may be novel and unobvious in view of the preamble or active steps.

The methods of Group I, III, and IV differ in the method objectives, method steps and parameters and in the reagents used. The instant specification does not disclose these methods would be used together. Group I is directed to detecting the expression of isoenzyme variants, Group III is directed to a method of treating a patient with nucleotides, and Group IV is directed to a different treatment method of a patient with antibodies or other biological agents. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for Group I differs significantly from Group III and IV for each of the materials and steps. For these reasons the Inventions Group I, III, and IV are patentably distinct.

Furthermore, the distinct method steps and products of invention Groups I, III, and IV have a separate status in the art as shown by their different classifications and require separate searches. Searching the inventions of Groups I, III, and IV together would impose serious search burden. Prior art which teaches method for Group II would not necessarily be applicable to the method of treating the patients in Group III or IV and a prior art which teaches method for Group III or IV would not necessarily be applicable to the method of detection of the expression o isoenzyme variants.

Election of species

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. HAS1 Va, HAS1 Vb, HAS1 Vc, HAS2.
B. SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:10.
C. Antisense DNA, antisense RNA, small inhibitory RNA
D. Peptide, antibody and fragment, vesnarinone, hyaluronic acid.
E. Multiple myeloma, waldenstrom's macroglomulemia

In the event that applicant elects Group I, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group A for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims reciting HAS isoenzyme variants are generic claims.

In the event that applicant elects Group II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group B for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects Group III, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group A or B and C for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects Group IV, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group A or B and D for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects Group II and V, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group A or B or E for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LY

Karen A. Canella

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